

Attorney Docket No: 10123/00801 (03-325)

**REMARKS**

Claims 1 - 21 remain pending in the present application. In view of the following remarks, it is respectfully submitted that all of the pending claims are allowable.

Claims 1 - 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by Mikhail (U.S. Patent 5,707,357).

Claim 1 recites "[a] pressure actuated valve for controlling the flow of fluid through a medical device," which includes "a flow control membrane... including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen." (See Specification, ¶¶ [0016] - [0017]).

The Applicants respectfully disagree with the Examiner's contention that claim 1 does not include any limitations requiring that the valve be opened by fluid pressure. Claim 1 clearly recites a "pressure actuated valve" including "a fluid control membrane" including slits opening when the membrane is "acted upon by a pressure of at least a threshold magnitude." It is respectfully submitted that, as made clear by the preamble to the claim and as made further clear by the specification which describes only fluid pressures as opening the disclosed valves, the "pressure" recited in claim 1 is fluid pressure. Furthermore, as described in detail in the specification the pressure of a "predetermined magnitude" is a fluid pressure sufficient to separate the edges of the slit in the membrane. No other type of pressure (e.g., manual pressure) is ever shown or suggested in the claim as opening the valve. In fact, as described in the application other mechanical closures (e.g., clamps) may damage catheters rendering them unsatisfactory. (Paragraphs [0004] and [0014]). Throughout the specification, the terms pressure and flow pressure are used interchangeably and thus, it is submitted that the recitation in claim 1

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of “[a] pressure actuated valve for controlling the flow of fluid through a medical device,” which includes “a flow control membrane... including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen,” clearly refers to a fluid pressure.

The Examiner also contends that there must be a flow pressure at which the valve of Mikhail must open. However, Mikhail describes “a palpitatable valve that may be selectively manipulated by the patient.” (See Mikhail, col. 6, lines 2 - 4). That is, the valves of Mikhail are opened only through manual actuation -- squeezing the valve. Mikhail does not contemplate or suggest that the palpitatable valve can be opened by fluid pressure. There is no reason whatsoever to assume that the palpitatable valve could successfully open in response to “a pressure of at least a threshold magnitude,” as recited in claim 1 nor is there any reason to assume that such an opening would not represent a failure of the valve. Mikhail describes a process by which the palpitatable valve opens in response to *inward radial pressure*, which is exerted by *manual squeezing*. (*Id.* at col. 22, lines 42 - 62). Thus, Mikhail’s valve is specifically designed to open using manual pressure. The use of fluid pressure is completely against the teachings of Mikhail, as the device is designed to retain urine by resisting the natural pressure of bladder fluid. (*Id.* at col. 2, lines 8 - 21). In fact, Mikhail specifically teaches away from the use of predetermined operational pressure ranges. (*Id.*). Any opening of this valve due to fluid pressure would cause leakage and would represent a failure of the valve. Thus, Mikhail teaches against opening in response to any kind of fluid pressure. In addition to being undesirable, the opening of the valve in response to fluid pressure would necessarily represent a failure of Mikhail’s device, indicating a structural or material defect, since opening to fluid pressure would never happen under normal circumstances. Assuming it were possible to open the valve using a sufficient fluid pressure, such force would indicate that Mikhail’s device was damaged, which completely defeats the entire purpose of Mikhail’s device.

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For these reasons, it is respectfully submitted that Mikhail neither discloses nor suggests “a pressure actuated valve” including “a flow control membrane... including a plurality of slits extending therethrough, wherein, *when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen,*” as recited in claim 1.

In addition, claim 1 recites “a plurality of slits...wherein each of the slits extends between end portions thereof along a curve and *wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits.*” This configuration of slits is most simply illustrated by Fig. 5 of the instant application. In contrast, none of the slit configurations shown in Mikhail show or suggest this limitation. Thus, it is respectfully submitted that none of the valves disclosed by Mikhail disclose or suggest a plurality of slits...wherein each of the slits extends between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits,” a recited in claim 1. Because claims 2 - 9 depend from, and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 10 recites a flow control device for a pressure actuated valve, comprising “a *substantially planar elastic membrane* including a peripheral seating portion adapted to be secured to a housing of the pressure actuated valve and a central portion including a first curved slit extending therethrough, the elastic membrane biasing the first slit to a closed configuration in which edges of the first slit are in contact with one another to prevent flow past the membrane, wherein, *when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane moves to an open configuration in which the edges of the first slit are separated from one another so that fluid may flow past the membrane through the first slit.* flow control device comprising “a substantially planar elastic membrane.” It is respectfully submitted that this claim is allowable for the same reasons stated above in regard to claim 1.

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In addition, it is noted that each of the valves of Mikhail is a "dome-type" valve. (Mikhail, col. 27, ll. 6-55; Fig. 3.) That is, the valves are dome shaped and are not substantially planar as recited in claim 10. The Examiner asserts that the term "planar" means lying in a plane. However, this reading is inconsistent with the common definition of the term planar, which means flat or level. This definition of planar is well-known to those skilled in the art and is even used repeatedly throughout Mikhail. For instance, Mikhail describes a mandril with a "generally flat or planar section" and deforming the valve into a "flat or planar configuration." (See, Mikhail, col. 24, lines 44 - 60). Thus, it is respectfully submitted that Mikhail neither discloses nor suggests "a substantially planar elastic membrane," as recited in claim 10. Because claims 11 - 16 depend from, and, therefore, include all of the limitations of claim 10, it is respectfully submitted that these claims are also allowable.

Claim 17 recites a catheter comprising "a pressure actuated valve" including "a flow control membrane extending across the lumen, the membrane including a first curved slit extending therethrough, wherein... *when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane deforms to an open configuration in which edges of the first slit separate from one another to allow flow through the lumen.*" It is respectfully submitted that claim 17 is allowable for the same reasons stated above in regard to claim 1. Because claims 18 and 19 depend from, and, therefore, include all of the limitations of claim 17, it is respectfully submitted that these claims are also allowable.

Claim 20 recites a valve including "a flow control membrane extending across a lumen of the device, the membrane including a plurality of slits extending therethrough, the slits being configured so that, *when the membrane is subjected to a flow pressure of at least a threshold magnitude, the slits open to permit flow through the lumen.*" It is respectfully submitted that this claim is allowable for the reasons stated above in regard to claim 1.

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Claim 21 recites a catheter including "a flow control membrane extending across a lumen thereof to regulate flow through the lumen and to seal the catheter when not in use, the membrane including a first curved slit extending therethrough, the slit being configured so that... *when the membrane is subject to a flow pressure of at least the predetermined threshold magnitude*, the edges of the slit separate from one another to permit flow past the membrane." It is respectfully submitted that this claim is allowable for at least the reasons stated above in regard to claim 1.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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